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DATE MAILED: 09/10/2002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,063	07/11/2001	Jack R. Wands	21486-032DIV3	1087
7	590 09/10/2002			
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY and POPEO, P.C. One Financial Center			EXAMINER	
			CANELLA, KAREN A	
Boston, MA 02111			ART UNIT	PAPER NUMBER
•			1642	C

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/903,063

Applicant(s)

Art Unit

Examiner

Karen Canella

1642

Wands et al



	The MAILING DATE of this communication appear	rs on the cover sheet with the correspondence address				
	for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 days MONTH(S) FROM						
THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the						
mailing date of this communication.						
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.						
- Failure - Any re	to reply within the set or extended period for reply will, by statute, cause the ply received by the Office later than three months after the mailing date of the	le application to become ABANDONED (35 U.S.C. § 133). his communication, even if timely filed, may reduce any				
earned	patent term adjustment. See 37 CFR 1.704(b).					
Status	December to accomplished an					
1) 🗆	Responsive to communication(s) filed on	<b>i</b>				
2a) ∐ —	This action is FINAL. 2b) 💢 This action					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.						
•	tion of Claims					
4) 💢	Claim(s) <u>1-38</u>	is/are pending in the application.				
4	a) Of the above, claim(s)	is/are withdrawn from consideration.				
5) 🗆	Claim(s)	is/are allowed.				
6) 🗆	Claim(s)	is/are rejected.				
7) 🗆	Claim(s)	is/are objected to.				
8) 💢	Claims <u>1-38</u>	are subject to restriction and/or election requirement.				
Application Papers						
9) The specification is objected to by the Examiner.						
10) ☐ The drawing(s) filed on is/are a) ☐ accepted or b) ☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11)□		is: a) $\square$ approved b) $\square$ disapproved by the Examiner.				
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority	under 35 U.S.C. §§ 119 and 120					
13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) 🗌 All b) 🔲 Some* c) 🔲 None of:						
1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No.					
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).						
*See the attached detailed Office action for a list of the certified copies not received.						
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).						
a)   The translation of the foreign language provisional application has been received.						
15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachn	nent(s)					
1)	otice of References Cited (PTO-892)	4) Interview Summary (PTO-413) Paper No(s).				
2) No	otice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal Patent Application (PTO-152)				
3) 🗌 lm	formation Disclosure Statement(s) (PTO-1449) Paper No(s)	6) Other:				

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## **DETAILED ACTION**

## Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9, and 28 drawn to methods for diagnosing and prognosing a malignant neoplasm and methods of killing tumor cells, said methods comprising contacting a bodily fluid with an Ab that binds to an HAAH polypeptide, classified in class 435, subclass 7.1.
  - II. Claims 10-15, drawn to a method for inhibiting tumor growth comprising administering a compound which inhibits the expression of HAAH, classified in class 514, subclass 44.
  - III. Claims 16-27, drawn to a method of inhibiting tumor growth comprising administering a compound which inhibits the enzymatic activity of HAAH or signal transduction through the IRS signaling pathway, classified, for example, in class 514, subclass 21.
  - IV. Claims 37 and 38, drawn to methods for determining whether a candidate compound inhibits HAAH enzymic activity or the HAAH activation of NOTCH, classified in class 435, subclass 7.4.
  - V. Claims 29-36, drawn to antibodies which bind to an epitome of HAAH and kits thereof, classified in class 530, subclass 387.1.
- 2. The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I, II, III and IV differ in the method objectives, method steps and parameters and in the reagents used.

Inventions V are related to Inventions I and II as product and multiple process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (M.E.P. § 806.05(h)). In the instant case the antibody of Invention V can be used in any of the methods I-IV, and in addition, can be used in a pocess of raising an anti-idioytpic antibody.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an 3. election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner 4. should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. Jun A. Gamelle

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

September 9, 2002